

## Notice of Allowability

**Application No.**

08/916,140

**Applicant(s)**

SCOTT ET AL.

**Examiner**

Richard Schnizer, Ph. D

**Art Unit**

1635

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/04/04.
2. ☒ The allowed claim(s) is/are 61,62,71 and 81.
3. ☒ The drawings filed on 02 February 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|   | 9. <input type="checkbox"/> Other _____.   |

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Melissa Rones on 12/03/04.

The application has been amended as follows:

#### IN THE SPECIFICATION:

At page 1, line 4, insert --(now US Patent 6,027,882, issued 2/2/2000)-- immediately after "08/656,055."

At page 1, line 5, insert --(now US Patent 5,837,538, issued 11/17/1998)-- immediately after "08/540,406."

At page 4, line 8, delete "L" and substitute --N-- therefor.

Replace the ABSTRACT with the following.

--Methods are provided for identifying agents that decrease hedgehog signal transduction for ameliorating an effect of loss of function of a *patched* gene in a mammalian cell.--

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IN THE CLAIMS:

Claims 1-60 (Cancelled)

Claim 61. (Currently amended) A method for identifying an agent that decreases hedgehog signal transduction for ameliorating an effect of loss of function of a patched gene in a mammalian cell, comprising:

- (i) contacting a hedgehog protein with a mammalian cell in culture that expresses a wild-type patched protein,
- (ii) contacting one or more test agents with said mammalian cell, and
- (iii) identifying one or more of said test agents that decrease the level of hedgehog signal transduction stimulated by said hedgehog protein relative to that present in the absence of said one or more test agents, wherein an agent that decreases hedgehog signal transduction is useful for ameliorating an effect of a loss of patched-mediated hedgehog signal transduction in a mammalian cell [[characterized by a loss of function of a patched gene]].

Claim 62. (Currently amended) A method for identifying an agent for ameliorating an effect of loss of function of a patched gene in a mammalian cell, comprising:

- (i) contacting a hedgehog protein with a mammalian cell in culture ~~characterized by an increased level of hedgehog signal transduction~~ , wherein the mammalian cell actively transduces a hedgehog signal,
- (ii) contacting one or more test agents with said mammalian cell, and

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(iii) identifying one or more test agents that decrease the level of said hedgehog signal transduction relative to that present in the absence of said one or more test agents, wherein an agent that decreases the level of said hedgehog signal transduction is useful for ameliorating an effect of a loss of hedgehog signal transduction in a mammalian cell [[characterized by a loss of function of a patched gene]].

Claims 63-70 (Cancelled)

Claim 71 (Previously presented) The method of claim 61 or 62 wherein the cell characterized by a loss of function of a patched gene is a basal cell carcinoma cell.

Claims 72-80 (Cancelled)

Claim 81 (Currently amended) A method for ~~preparing~~ identifying an agent for inhibiting growth of cells characterized by a loss of function of a patched gene, comprising:

[a.] (i) contacting a hedgehog protein with a mammalian cell that expresses a wild-type patched protein, contacting one or more test agents with said mammalian cell, and identifying test agents that decrease the level of hedgehog signal transduction stimulated by said hedgehog protein in said cell relative to that present in the absence of the identified test agents;

[b.] (ii) contacting a hedgehog protein and test agents identified in step (i) with a mammalian cell having a loss of function of a patched gene, wherein said cell is a basal

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cell carcinoma cell, and selecting those test agents that inhibit growth of mammalian cells having a loss of function of a patched gene; and

~~[c.] — (iii) preparing a formulation including a test agent selected in step (ii) that inhibits the growth of mammalian cells ~~[[selected in step (b)]] and a pharmaceutically acceptable diluent.~~~~

### ***Examiner's Comment***

Claim 81 was previously drawn to a method for preparing a pharmaceutical formulation comprising an agent that inhibits the growth of a mammalian cell, which is not deemed patentable at this time. The claim is currently amended to more accurately reflect the essence of the invention, i.e. methods of identifying agents that decrease hedgehog signal transduction.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax

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number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.

DAJET NGUYEN  
PRIMARY EXAMINER

